REMARKS

Claims 1-41 are pending in the present application. Claims 7-9 and 20-22 were previously withdrawn from consideration as drawn to a non-elected invention. By virtue of this response, claims 1-26, 28-30, 32-35, and 37-40 have been cancelled, claims 27, 31, 36, and 41 have been amended and new claims 42-61 have been added. Accordingly, claims 27, 31, 36, and 41-58 are currently under consideration.

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and, moreover, have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation, continuation-in-part and/or divisional applications.

Interview Summary

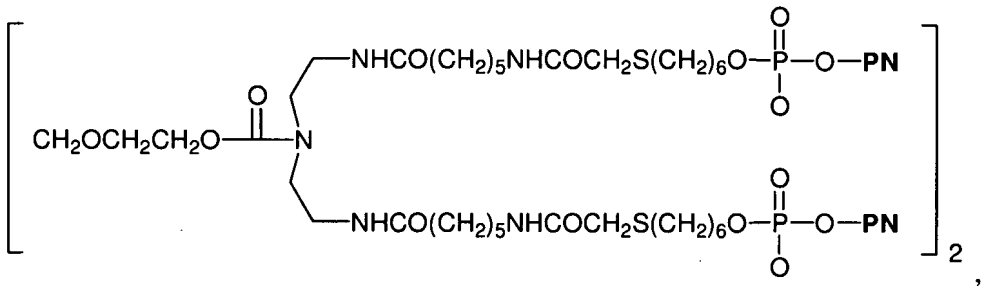
An in-person interview with Examiners Sajjadi and Woitach was held on January 23, 2008. In addition to Examiners Sajjadi and Woitach and Alicia Hager (the undersigned), Catherine Polizzi and Matthew Linnik participated in the interview. Applicants and their representatives would again like to thank both Examiners Sajjadi and Woitach for the courtesy of the interview.

The subject of the interview was the Final Office Action dated November 14, 2007. Claims discussed included claim 1. In addition, the Wallace reference cited in the Final Office Action was discussed. Possible responses to the rejections were also proposed and discussed.

Claim Amendments

Claims 1-26, 28-30, 32-35, and 37-40 have been cancelled, claims 27, 31, 36, and 41 have been amended, and new claims 42-61 have been added. No new matter is added.

Claim 27, as amended, is directed to a method of treating systemic lupus erythematosus (SLE) in a human individual, comprising administering to the human individual an effective amount of an agent, wherein the agent is administered in the form of a conjugate of the formula



wherein PN is $(CA)_{10}$•$(TG)_{10}$ ((SEQ ID NO:2)•(SEQ ID NO:1)), and determining if there is a sustained reduction of circulating anti-dsDNA antibodies in the individual of at least 10% below baseline for at least two months, wherein said sustained reduction indicates the effectiveness of the treatment. Support for this amendment is found throughout the application and, e.g., in paragraphs [0014], [0021], [0036], [0097], [0099]-[0101] and [0031].

Claim 47 is directed to a method of monitoring a treatment for SLE in a human individual, comprising determining if there is a sustained reduction of circulating anti-dsDNA antibodies in the individual of at least 10% below baseline for at least two months, wherein said sustained reduction indicates effectiveness of the treatment. Support for this new claim is found throughout the application and, e.g., in paragraphs [0021], [0097], and [0023].

Claim 51 is directed to a method of assessing the likelihood of success of a treatment for SLE in a human individual, comprising determining if there is a sustained reduction of circulating anti-dsDNA antibodies in the individual of at least 10% below baseline for at least two months, wherein said sustained reduction indicates the likelihood of success of the treatment. Support for this new claim is found throughout the application and, e.g., in paragraphs [0022], [0098], and [0023].

Claim 53 is directed to a method of assessing the likelihood of renal flare in a human individual with SLE, comprising determining if there is a sustained reduction of circulating anti-dsDNA antibodies in the individual of at least 10% below baseline for at least two months, wherein said sustained reduction indicates a decreased likelihood of renal flare. Support for this new claim is found throughout the application and, e.g., in paragraphs [0022], [0096], [0099], [0023], and [0031].

Minor, clarifiying amendments are made to claim 31. No new matter is added.

Claim 36 is amended to delete "a dose of" and add "to the individual per week." Support for the amendment is found in paragraph [0119].

Claim 41 is amended due to the cancellation of claims 1, 14, and 28.

Support for new dependent claims 42-46, 48-50, 52, and 54-61 is found throughout the application as filed and as indicated in the following table:

NEW CLAIM(S)	EXEMPLARY SUPPORT
42	Paragraph [0016]
43	Paragraph [0017]
44	Paragraph [0019]
45, 48	Paragraphs [0099], [0101], and [0033]
46, 49	Paragraph [0119]
50, 52	Paragraph [0177]
54-57	Paragraphs [0036] and [0081]
58	Paragraphs [0081] and [0032]
59	Paragraphs [0014], [0021], and [0022]
60	Paragraph [0021] and [0097]
61	Paragraph [0022]

Claim Rejections – 35 USC § 112, Second Paragraph

Claims 1-6, 10-19, 23-28, 30- 33 and 34 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1, 14, 27, 28, 30, 33 and 34 were allegedly unclear in the recitation of doses corresponding to 3 mg/kg or higher and 10 mg/kg or higher, because allegedly the doses failed to define an upper limit for the dose to be administered, and allegedly fail to define the metes and bounds of the claims.

Applicants respectfully traverse. Without acquiescing to the rejection and solely in the interest of expediting prosecution, Applicants have cancelled claims 1, 14, 28, 30, 33 and 34 and amended claim 27. The rejection of the cancelled claims is considered moot and Applicants will therefore focus their response on claim 27, as amended, and the new claims. Neither claim 27, as amended, nor any of the new claims, recites doses of "3 mg/kg or higher" or "10 mg/kg or higher." Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

B. Claims 1 and 14 were also allegedly unclear in their recitation of "and wherein if the agent is administered in the form of a conjugate of the formula...."

Applicants have cancelled claims 1 and 14. The rejection is therefore considered moot, and Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

New Claim Rejections – 35 USC § 112, First Paragraph (New Matter)

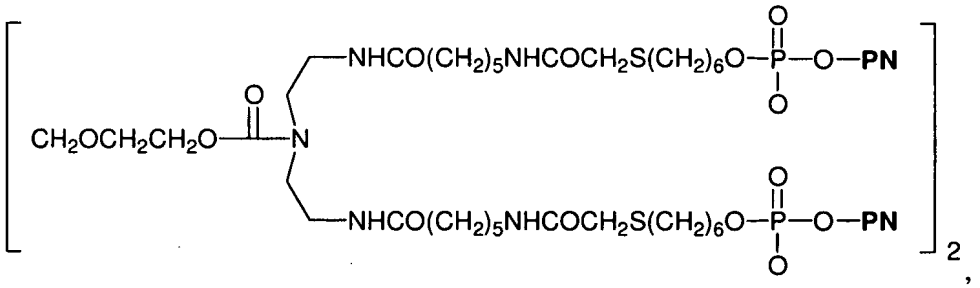
Claims 1-6, 10-19, and 23-41 stand newly rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. With respect to claims 1 and 14, the Examiner alleges that the "instant specification provides a written description

support for the claimed therapeutic limitations following administration of LJP394, and not other agents having a different conjugate formula." With respect to claims 1, 14, 27, 28, 30, 32, 33, 35-37, and 38-40, the Examiner alleges that the instant specification is devoid of the recited dose limitations.

Applicants respectfully traverse.

Without acquiescing to the rejection and solely in the interest of expediting prosecution, Applicants have cancelled claims 1, 14, 28, 30, 32, 33, 35-37, and 38-40 and amended claims 27, 31, 36, and 41. The rejection of the cancelled claims is considered moot and Applicants will therefore focus their response on claims 27, 31, 36, and 41, as amended, and the new claims.

Independent claim 27, as amended, is now directed to a method of treatment that comprises administering an agent in the form of a conjugate of the formula



wherein PN is $(CA)_{10}$•$(TG)_{10}$ ((SEQ ID NO:2)•(SEQ ID NO:1)). New independent claim 47 is directed to a method of monitoring a treatment, new independent claim 51 is directed to a method of assessing the likelihood of success of a treatment, and new independent claim 53 is directed to a method of assessing the likelihood of renal flare, and none of these new claims requires administration of any agent.

In addition, neither claim 27, as amended, nor any of the new claims, recites doses of "3 mg/kg or higher," "10 mg/kg or higher," or "a dose of about 300 mg." Accordingly, the rejection is moot with respect to these dose limitations.

Dependent claim 31, as amended, recites "administering the conjugate to the individual in doses of about 5 mg to about 100 mg of the conjugate per kg of the individual." Applicants respectfully contend that this claim is fully supported by the application.

It is well established that to meet the written description requirement, an applicant's specification must "convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath, Inc. v. Marhurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). This is the standard that the Federal Circuit has set. Literal support is not a requirement. With respect to numerical ranges in particular, MPEP 2163.05 states, "With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In the decision in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of "25%- 60%" and specific examples of "36%" and "50%." ... however a limitation to "between 35% and 60%" did meet the description requirement." Thus, in *In re Wertheim*, the description of a range and two values within the range was found to sufficiently disclose a new, narrower range within the described range.

Applicants contend that, based on paragraph [0119] of the present application, one of ordinary skill in the art would recognize the inventors to be in possession of the method of claim 31 involving a "dose of about 5 mg to about 100 mg of the conjugate per kg of the individual," and, therefore, the written description requirement is met. Applicants contend that the facts in the present case are largely analogous to the facts in *In re Wertheim* as summarized in MPEP 2163.05 and outlined above. Lines 10-13 of paragraph [0119] of the present application read, "Generally, a dose of about 1 μg to about 100 mg conjugate/kg body weight, preferably about 100 μg to about 10 mg/kg body weight, preferably about 150 μg to about 5 mg/kg body weight, preferably about 250 μg to about 1 mg conjugate/kg body weight." Thus, the specification in paragraph [0119] clearly describes the dose range of "about 1 μg to about 100 mg conjugate/kg body weight." Since the specification in paragraph [0119] also states "about 150 μg to about 5 mg/kg" and "about 100 μg to about 10 mg/kg," doses of "about 5 mg/kg" and "about 10 mg/kg" are also clearly described. The described dose amounts "about 5 mg/kg" and "about "10 mg/kg" are values within the described

dose range of "about 1 μg to about 100 mg conjugate/kg body weight" and, therefore, the narrower dose range of "about 5 mg/kg to about 100 mg of the conjugate per kg" is also fully disclosed.

Dependent claim 36, as amended, recites "administering about 200 mg to about 500 mg of the conjugate to the individual per week." Applicants respectfully contend that this claim is fully supported by the application.

Applicants contend that, based on paragraph [0119] of the present application, one of ordinary skill in the art would recognize the inventors to be in possession of "administering about 200 mg to about 500 mg of the conjugate...per week" as recited in claim 36, and therefore, the written description requirement is met. Lines 15-17 of paragraph [0119] of the present application read, "Other dosages, such as about 50 to 100 mg per week, 50 to 250 mg per week, and 50 to 500 mg per week (with any value inbetween the lower and upper limit of these ranges) are also contemplated." Since the specification clearly states "with any value inbetween the lower and upper limit of the ranges," the specification discloses all dosages between about 50 mg and about 500 mg per week, including those dosages between "about 200 to about 500 mg of the conjugate...per week."

In light of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn, and that the rejection not be applied to the newly added or amended claims.

Response & New Claim Rejections – 35 USC § 112, Scope of Enablement

Claims 1-6, 10-19, and 23-41 stand rejected under 35 U.S.C. § 112, first paragraph, because allegedly the specification fails to provide an enablement for the full scope of the claimed invention. The Examiner alleges that the "instant specification fails to provide an enablement for a method of treating systemic lupus erythematosus (SLE)...resulting in an indefinitely sustained reduction in anti-dsDNA antibody." The Examiner further alleges that the "patient population that responded to the treatment regimes with LJP 394 in a statistically significant manner was limited to the subpopulation of SLE patients having high affinity antibodies to LJP 394."

Applicants respectfully traverse this rejection.

Without acquiescing to the rejection and solely in the interest of expediting prosecution, Applicants have cancelled claims 1, 14, 28, 30, 32, 33, 35-37, and 38-40 and amended claims 27, 31, 36, and 41. The rejection of the cancelled claims is considered moot and Applicants will therefore focus their response on claims 27, 31, 36, and 41, as amended, and the new claims.

By virtue of this amendment, the phrase "wherein the administration of the agent results in a sustained reduction of anti-dsDNA antibody for at least about one month, wherein the sustained reduction is at least about 10% below baseline in the individual" has been removed, without prejudice, from independent claim 27. Instead, claim 27, as amended, now requires the step of "determining if there is a sustained reduction of circulating anti-dsDNA antibodies in the individual of at least 10% below baseline for at least two months, wherein said sustained reduction indicates the effectiveness of the treatment." New independent claims 47, 51, or 53 contain similar "determination" steps. Accordingly, amended claim 27, as well as each of the new independent claims, recites the determination of whether administration of an agent to an individual results in a sustained reduction of anti-dsDNA antibody for the recited period of time.

In light of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn, and that the rejection not be applied to the newly added or amended claims.

Response & New Claim Rejections – 35 USC § 102(b)

Claims 1-6, 10-19, and 23-41 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Wallace (Exp. Opin. Invest. Drugs 10:111-117; 2001).

Applicants respectfully traverse this rejection.

Without acquiescing to the rejection and solely in the interest of expediting prosecution, Applicants have cancelled claims 1, 14, 28, 30, 32, 33, 35-37, and 38-40 and amended claims 27,

31, and 36. The rejection of the cancelled claims is considered moot and Applicants will therefore focus on points of distinction with respect to claims 27, 31, 36, and 41, as amended and with respect to the new claims. However, Applicants note that points of patentable distinction also apply with respect to the cancelled claims and claims 27, 31, 36, and 41 prior to the present amendment.

Wallace et al. fails to anticipate (or render obvious) amended independent claim 27, because it does not teach (or suggest) a method of treating systemic lupus erythematosus (SLE) comprising determining if there is a sustained reduction of circulating anti-dsDNA antibodies in the individual of at least 10% below baseline for at least two months, wherein said sustained reduction indicates the effectiveness of the treatment.

Wallace et al. fails to anticipate (or render obvious) new independent claim 47, because it does not teach (or suggest) a method of monitoring a treatment for SLE in a human individual, comprising determining if there is a sustained reduction of circulating anti-dsDNA antibodies in the individual of at least 10% below baseline for at least two months, wherein said sustained reduction indicates effectiveness of the treatment.

Wallace et al. fails to anticipate (or render obvious) new independent claim 51, because it does not teach (or suggest) a method of assessing the likelihood of success of a treatment for SLE in a human individual, comprising determining if there is a sustained reduction of circulating anti-dsDNA antibodies in the individual of at least 10% below baseline for at least two months, wherein said sustained reduction indicates the likelihood of success of the treatment.

Wallace et al. fails to anticipate (or render obvious) new independent claim 53, because it does not teach (or suggest) a method of assessing the likelihood of renal flare in a human individual with SLE, comprising determining if there is a sustained reduction of circulating anti-dsDNA antibodies in the individual of at least 10% below baseline for at least two months, wherein said sustained reduction indicates a decreased likelihood of renal flare.

In light of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 102, be withdrawn, and that the rejection not be applied to the newly added or amended claims.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 252312008000. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: May 14, 2008

Respectfully submitted,

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